



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Laboratory Animal Welfare: Adoption and Implementation of the Eighth Edition of the *Guide for the Care and Use of Laboratory Animals*

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) has analyzed public comments received regarding adoption and implementation of the 8th Edition of the *Guide for the Care and Use of Laboratory Animals (Guide)* and has determined to adopt the 8th Edition of the *Guide*. (The comments, received by NIH from February 24 to May 24, 2011, may be viewed at http://grants.nih.gov/grants/olaw/2011guidecomments/web_listing.htm). In NIH's judgment, the 8th Edition of the *Guide* empowers continued advancement in the humane care and use of vertebrate animals in research, research training, and biological testing.

Effective January 1, 2012, institutions that receive Public Health Service (PHS) support for animal activities must base their animal care and use programs on the 8th Edition of the *Guide*

and must complete at least one semiannual program review and facilities inspection using the 8th Edition of the *Guide* as the basis for evaluation by December 31, 2012. It is not required that all necessary changes be completed by December 31, 2012, but rather that an evaluation must be conducted and a plan and schedule for implementation of the standards in the 8th Edition of the *Guide* must be developed by December 31, 2012. Institutions must verify to the Office of Laboratory Animal Welfare (OLAW), the organizational component of NIH that provides guidance and interpretation of the PHS Policy on Humane Care and Use of Laboratory Animals, that they have met the required schedule. This will be done through the Annual Report to OLAW covering the 2012 reporting period due January 31, 2013. In addition, institutions must document the implementation of the 8th Edition of the *Guide* in their next Animal Welfare Assurance renewal.

OLAW has developed Position Statements located at <http://grants.nih.gov/grants/olaw/2011positionstatement.htm>. The Position Statements clarify the ways in which NIH expects Assured institutions to implement the 8th Edition of the *Guide* by addressing the following concerns: cost of implementing the 8th Edition of the *Guide*; animal housing specifications; use of nonpharmaceutical-grade compounds; food and fluid restrictions; multiple surgical procedures; and application of the 8th Edition of the *Guide* to agricultural animals used in biomedical research. In addition, there is a summary of OLAW's position on performance standards and practice standards. The public is invited to submit comments on their understanding of the Position Statements for a period of 60 days from December 1, 2011, to January 29, 2012. In response, OLAW may further clarify the Position Statements.

DATES: Written comments on the public's understanding of the Position Statements must be received by NIH on or before January 29, 2012, to be considered.

ADDRESSES: Public comments on the Position Statements may be entered at <http://grants.nih.gov/grants/olaw/2011positionstatement.htm>. Comments will be made publicly available. Personally identifiable information (except organizational affiliations) will be removed prior to making comments publicly available.

FOR FURTHER INFORMATION CONTACT: Office of Laboratory Animal Welfare, Office of Extramural Research, National Institutes of Health, RKL1, Suite 360, 6705 Rockledge Drive, Bethesda, MD 20892-7982; or telephone: 301-496-7163.

SUPPLEMENTARY INFORMATION:

I. Background

Since 1985, the PHS Policy on Humane Care and Use of Laboratory Animals, authorized by P.L. 99-158, 42 U.S.C. §289d, and incorporated by reference at 42 C.F.R. §52.8 and 42 C.F.R. §52a.8, has required that institutions receiving PHS support for animal activities base their animal care and use programs on the current edition of the *Guide*. Since 1996, programs have been based on the 7th Edition of the *Guide*. The 8th Edition of the *Guide* was published in January 2011, following a study by the Institute for Laboratory Animal Research of the National Academy of Sciences. The 8th Edition of the *Guide* contains substantive changes and additions from the previous edition. To gain insight from institutions on the impact of changes to the

Guide on their animal care and use programs, NIH sought comments on whether it should adopt the 8th Edition of the *Guide* and on the proposed implementation plan. On February 24, 2011, NIH issued a *Federal Register* Notice (see <http://edocket.access.gpo.gov/2011/pdf/2011-4172.pdf>) requesting public comments on (1) NIH's adoption of the 8th Edition of the *Guide* as a basis for evaluating institutional programs receiving or proposing to receive PHS support for activities involving animals and (2) NIH's proposed implementation plan (if NIH decided to adopt the 8th Edition of the *Guide*). The original implementation plan proposed that institutions complete at least one semiannual program and facility evaluation using the 8th Edition of the *Guide* as the basis for evaluation by March 31, 2011.

Comments were collected via the Internet through a Web link available in the *Federal Register* and on the OLAW Web site, where respondents could also access both the 7th and 8th Editions of the *Guide*. The original comment period was scheduled from February 24, 2011, to March 24, 2011. This comment period was extended twice, on March 18 and April 21. Ultimately, the comment period spanned 90 days, closing on May 24, 2011. In addition to the time extension, the NIH removed the original 6,000-character limit on the comment form fields in the April 21 extension to maximize the opportunity for individuals and organizations to provide comments to NIH. A total of 806 responses were submitted by Assured institutions, professional organizations, animal advocacy organizations, and individuals. The comments and an analysis may be viewed at http://grants.nih.gov/grants/olaw/2011guidecomments/web_listing.htm.

II. Electronic Access

The 8th Edition of the *Guide* is available on the OLAW Web site at <http://olaw.nih.gov>.

Dated: November 22, 2011

Francis S. Collins, M.D., Ph.D.

Director,

National Institutes of Health

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